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FAEGRE & BENSON LLP
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2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/680,734	Applicant(s) GOLDENBERG ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 8/22/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1, 6, 7, 10, 11, 44, 49-51 and 108 is/are pending in the application.

4a) Of the above claim(s) 44 and 49-51 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 6, 7, 10, 11 and 108 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/22/07 has been entered.

2. Claims 1, 6, 7, 10, 11, 44, 49-51 and 108 are all the pending claims for this application.

3. Claims 1, 10, 11 and 108 were amended and Claim 55 was cancelled in the Response of 8/22/07.

Claims for the apoptosis agents find support in the original specification and as evidenced by the publications submitted with the Response:

Nowak et al. (J. Immunol. 170:4905-13, 2003)- gemcitabine
Ray et al. (Cancer Res. 63:4713-23, 2003)- CPT-11
Rigas et al., (Abstract, Cancer Invest. 20:657-65, 2002)- 5-FU
Mani et al. (Abstract, Oncol. 14:52-8, 2000)- oxaliplatin
Groninger et al. (Abstract, Int. J. Oncol. 21:1339-45, 2002)- vincristine
Tsang et al. (Abstract, Life Sci. 73:2047-58, 2003)- doxorubicin
Shibuya et al. (Abstract, Melanoma Res. 13:457-64, 2003)- dacarbazine (DTIC)
Ueno et al. (Abstract, Eur. Urol. 42:390-7, 2002)- CPT-11

Simoes-Wust et al. (Breast Cancer Res. 76:157-66, 2002)- cyclophosphamide

4. Claims 44 and 49-51 are withdrawn from examination.

5. Claims 1, 6, 7, 10, 11 and 108 are all the claims under examination.

Withdrawal of Rejections

Claim Rejections - 35 USC § 102

6. The rejection of Claims 1 and 10 under 35 U.S.C. 102(e) as being anticipated Cheung (US 20060160766: published July 20, 2006; with priority to U.S. provisional 60261911, filed 1/16/2001) is withdrawn.

Applicants' allegations on pp. 7-8 of the Response of 8/22/07 have been considered and are found persuasive. Cheung does not teach or suggest treating human medullary thyroid carcinoma with the antibody of Cheung, or that the antibody could synergize with an apoptosis agent to produce an improved effect in human colon cancer.

Note- The Examiner respectfully submits that because the composition is only enabled for using the MN-14 antibody (or huMN-14) in combination with an apoptosis agent in order to achieve a synergistic effect in treating human medullary thyroid carcinoma or human colon cancer (see discussion below), the rejection over Cheung is withdrawn because Cheung does not teach the MN-14 antibody.

Claim Rejections - 35 USC § 103

7. The rejection of Claims 1, 6, 10, 11 and 108 under 35 U.S.C. 103(a) as being obvious over Cheung (US 20060160766: published July 20, 2006; with priority to U.S. provisional 60261911, filed 1/16/2001) as applied to Claims 1 and 10 (discussed supra) and further in view of Hansen et al. (USPN 5,874,540; cited in the 892 form of 5/25/06) and Griffiths et al. (USPN 7,001,812; cited in the 892 form of 10/19/06) is withdrawn for the reasons discussed supra regarding Cheung.

Double Patenting

8. The rejection of Claims 1, 6, 10, 11 and 108 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 10 of Griffiths et al. (U.S. Patent No. 7,001,812) in view of Hansen (USPN 5,874,540) and Govindan et al. (US20040001825) is withdrawn in view of Applicants' amendment of Claim 1 to recite that the composition is effective for "human medullary thyroid carcinoma or human colorectal cancer".

Applicants' allegations on p. 6 of the Response of 8//22/07 that none of the references teach the instant limitation of Claim 1 are acknowledged.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

9. The rejection of Claims 1, 6, 7, 10, 11 and 108 under 35 U.S.C. 112, first paragraph, in lacking enablement for any combination therapy (any anti-CEA-antibody with any apoptotic agent) producing a synergistic effect in treating human medullary thyroid carcinoma or human colorectal cancer is maintained.

Applicants have amended Claim 1 to a composition a) required to have an treatment effect on "human medullary thyroid carcinoma or human colorectal cancer" in combination with b) any "apoptosis agent" and any "naked anti-CEA MAb is unreactive with normal cross-reactive antigen (NCA) and meconium antigen (MA), and is a naked humanized anti-CEA antibody having an IgG 1 human constant region" in order to c) produce a syngeristic (more effective) treatment effect, but the amendments do not overcome the rejection. Applicants allege on pp. 6-7 of the Response of 8/22/07 "the only types of cancer in which the combination must be synergistic is limited to human medullary thyroid carcinoma or human colorectal cancer"...and only "apoptotic agents" are to be used in the combination therapy.

The Examiner respectfully submits that Claim 1 encompasses any anti-CEA Mab (other then MN-14 of Claims 6 and 7), any apoptosis agent (other than those in Claims

10, 11 and 108) and any combination, which are not enabled by the specification as set forth in the Office Action of 6/6/07.

For example, Example 9 of the specification describes using antibodies targeting different epitopes than huMN-14 (i.e., NP1, NP3, MN3, MN15; (Sharkey, R. M., et al., Cancer Res, 50:2823-2831,1990). But it is not readily apparent from the discussion whether and how these antibodies performed differently than the MN-14 antibody under the same test conditions. Thus, absent a further showing, Applicants have only disclosed the MN-14 antibody having the instant claimed properties. Applicants' specification does not disclose any other antibody than huMN-14 having a synergistic effect in combination with selected apoptosis agents for treating "human medullary thyroid carcinoma or human colorectal cancer". Thus Applicants have not demonstrated a reasonable number of embodiments under the *Wands* decision (8 USPQ2d 1400 (Fed. Cir. 1988)) for the anti-CEA Mabs meeting the limitation of step (i). Applicants have not demonstrated a reasonable number of embodiments of compositions comprising the anti-CEA Mab of step (i) in combination with any apoptosis agent having a synergistic effect on "human medullary thyroid carcinoma or human colorectal cancer". Absent an enabling disclosure for the scope of the claims, one of ordinary skill in the art at the time of filing would not have been enabled to have practiced the scope of the invention for Claim 1 without undue experimentation.

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al. (Cancer 94:51-61 (1/1/2002)) and Blumenthal et al. (54:142-151 (1994) Abstract).

The interpretation of Claims 1, 10 and 11 is discussed supra.

The claimed composition was prima facie obvious at the time of the invention over Stein and Blumenthal.

Stein teaches compositions for treating nude mice bearing human medullary thyroid tumor comprising the anti-CEA Mab MN-14 in combination with the apoptosis agents, doxorubicin, DTIC, cyclophosphamide, and vincristine, to produce a synergistic effect “significantly enhanced over that observed with either single modality therapy” (p.

59, Col. 2, ¶1). Stein does not teach the using the compositions on human colon cancer but Blumenthal teaches anti-CEA Mab (MN-14) and 5-FU in treating human colon cancer.

Blumenthal compares the effect of conventional 5-FU and MN-14 Mab on human xenograft tumor cell lines (LoVo, HT-29, DLD-1, HCT-15, LS174T, Moser, Gw-39 and WidR) in mice. Blumenthal suggests that MN-14 therapy may have advantages over conventional 5-FU therapy alone.

One skilled in the art would have been motivated to have produced and been reasonably assured of success in having produced the instant claimed compositions over Stein and Blumenthal. Each of the references teach the comparison between the HM-14 Mab and apoptosis agents in treating a human cancer, where each of the references concludes independently, that the HM-14 Mab is more effective than the conventional apoptosis therapy alone. Stein discloses using the reagents in combination (MN-14 Mab and doxorubicin, DTIC, cyclophosphamide, and vincristine) to synergize in treating human thyroid medullary cancer. Stein does not exclude treating other cancers with MN-14 and Blumenthal provides the motivation to use the composition for the purpose of treating human colon cancer. Because the synergistic effects of the MN-14 antibody and apoptosis reagents was inherent to the composition for treating human medullary tumors of Stein, one skilled in the art would have been further motivated to have considered the composition of Stein in view of Blumenthal's disclosure for treating human colon cancers because Blumenthal specifically taught that HM-14 was improved over 5-FU alone. One skilled in the art would have been reasonably assured of success in having combined the reference disclosure to obtain the instant claimed composition because Stein and Blumenthal has demonstrated success in using the MN-14 Mab in cancer therapy and Stein extended the utility of the MN-14 Mab by showing that it could synergize with apoptosis agents. For all of the foregoing reasons, the claims were prima facie obvious at the time of the invention over Stein and Blumenthal.

11. Claims 1, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al. (Cancer 94:51-61 (1/1/2002)) in view of Blumenthal et al. (54:142-151 (1994) Abstract) as applied to claim 1 above, and further in view of Hansen (USPN 5,874,540); cited in the IDS of 9/14/06).

The interpretation of Claims 1, 6 and 7 is of record.

The claimed composition comprising a humanized MN-14 antibody and having framework substitutions was prima facie obvious at the time of the invention over Stein, Blumenthal and Hansen.

The interpretation of Stein and Blumenthal is discussed supra. Neither reference teaches humanized forms of MN-14 Mab with framework substitutions.

Hansen discloses a humanized Class III anti-CEA mAb in which the CDRs of a murine Class III anti-CEA mAb (MN14) are functionally engrafted to the amino acid sequence of a human antibody or antibody fragment to provide an immunological reagent with the anti-CEA binding properties of the murine Class III, anti-CEA mAb (see specification in general; Col. 2, lines 3-9; Figures 3 and 4; Example 8). A chimeric Class III anti-CEA mAb is also disclosed where the VH and VL regions from the murine Class

III anti-CEA mAb (MN14) are functionally engrafted to the amino acid sequence of a human antibody or antibody fragment (Figures 3 and 4). The MN-14 Mab meets all of the criteria of a Class III, anti-CEA monoclonal antibody, being unreactive with meconium antigen (MA) by EIA and not reacting with normal tissues (i.e., unreactive with normal cross-reactive antigen (NCA)) (Col. 5, lines 61-67). The humanized and chimeric Class III anti-CEA mAb are disclosed as having the following CDRs: CDR.sub.L1, has the amino acid sequence KASQDVGTSVA (SEQ. ID NO. 20); CDR.sub.L2 has the amino acid sequence WTSTRHT (SEQ. ID NO. 21); CDR.sub.L3 has the amino acid sequence QQYSLYRS (SEQ. ID NO. 22); CDR.sub.H1 has the amino acid sequence TYWMS (SEQ. ID. NO. 23); CDR.sub.H2 has the amino acid sequence EIHPDSSTI NYAPS LKD (SEQ. ID NO. 24); and, CDR.sub.H3 has the amino acid sequence LYFGF PWFAY (SEQ. ID NO. 25). Hansen specifically discloses using the antibody to treat human colon carcinoma. Hansen teaches the MN-14 heavy chain VH framework regions are different from those in the framework regions of other subgroup IIIB VH sequences at four substitutions (Ser 14, Thr 30, Ser 98 and Pro 108) which are advantageous to the binding of murine MN-14. Hansen teaches that the effect of humanizing the antibody is to reduce the development of HAMA and ensure that more of the antibody reaches the target tissue.

One skilled in the art at the time of the invention would have been motivated to have produced the instant composition and been reasonably assured of success based on the combined disclosures of Stein, Blumenthal and Hansen. The motivation to combine and the assurance of success in combining Stein and Blumenthal is discussed supra. One skilled in the art would have found prima facie motivation to improve the property of the antibody in the composition by humanizing the CDRs from MN-14 while retaining essential murine framework residues in the engrafted human acceptor based on the disclosure of Hansen that such changes would reduce the immunogenicity of the molecule in treatment methods. Hansen specifically taught the humanized antibody having the VHCDR1-3 and VLCDR1-3 of instant Claim 6 for use treating human colon cancers, and both Stein taught treating medullary cancers and Blumenthal taught treating human colon cancer with MN-14 Mab. Thus the ability to target these cancers was prima facie inherent to the Mab at the time of the invention. To have obtained an even more effective composition comprising a humanized MN-14 Mab in treating cancers, Stein taught that the MN-14 Mab could be used in combination with apoptosis agents and the resultant effects were enhanced over the individual molecules alone. The combined reference disclosures provided more than sufficient motivation and reasonable assurance to one of ordinary skill in the art that the humanized MN-14 antibody could be substituted for the MN-14 Mab of Stein or Blumenthal without compromising the ability of the antibody to mediate an effect and further that the humanized form would retain it's inherent characteristics for synergizing with apoptosis agents in treating the human cancers. For all the foregoing reasons, the claimed compositions were prima facie obvious at the time of the invention.

11. Claims 1, 10 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al. (Cancer 94:51-61 (1/1/2002)) in view of Blumenthal et al. (54:142-151 (1994) Abstract) as applied to claim 1 above, and further in view of Griffiths et al. (US 20040043030; published 3/4/04; filed 7/31/02) and Mani et al. (Abstract, Oncol. 14:52-8, 2000).

The interpretation of Claims 1, 10 and 108 is of record.

The interpretation of Stein and Blumenthal regarding the motivation and assurance of success in having produced the composition is discussed supra. One skilled in the art would not have been precluded from introducing other apoptosis agents into the composition and that were known to have a therapeutic effect on human thyroid and colon cancer in combination with the MN-14 Mab.

Stein and Blumenthal teach the apoptosis agents, doxorubicin, DTIC, cyclophosphamide, vincristine and 5-FU, but do not teach CPT-11, dacarbazine oxaliplatin and gemcitabine. Neither reference teaches combining an MN-14 Mab with CPT-11, dacarbazine, oxaliplatin and gemcitabine.

Griffiths teaches combining MN-14 Mab with CPT-11, dacarbazine, and gemcitabine in treating colon cancer.

Mani teaches treating human colorectal cancer with oxaliplatin in combination with other agents.

It would have been prima facie obvious to have combined the apoptosis agents of Griffiths and Mani with the composition of Stein in order to have the MN-14 antibody synergize with the agents in treating a human thyroid cancer as taught by Stein and a human colon cancer as taught by Blumenthal because the references disclosed that MN-14 was effective at targeting the two cancer types, MN-14 therapy could be combined with apoptosis agents and that the combination would synergize.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 6, 7, 10, 11 and 108 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 10 of Griffiths et al. (U.S. Patent No. 7,011,812; cited in the PTO form 10/19/06) in view of Stein et al. (Cancer 94:51-61 (1/1/2002), Blumenthal et al. (54:142-151 (1994)) and Hansen (USPN 5,874,540; cited in the IDS of 9/14/06).

The interpretation of the claims is of record and discussed supra.

The claimed composition comprising a CEA Mab and apoptosis agent was prima facie obvious at the time over claims 1, 2, and 10 of Griffiths in view of Hansen, Stein and Blumenthal.

Griffiths claims a composition for effecting therapy of a tumor in a patient, comprising a therapeutic naked antibody and a second therapeutic agent (Claim 1), where the therapeutic agent is a drug (Claim 2), where the drug is a nitrogen mustard, a triazene, a vinca alkaloid, and an antibiotic (Claim 10). Griffiths discloses a humanized anti-CEA antibody (MN-14) as an antibody in the composition. Griffiths discloses species for the following drugs: cyclophosphamide (nitrogen mustard), DTIC (triazene), vincristine (vinca alkaloid), doxorubicin (antibiotic) and the prodrug CPT-11 (irinotecan) as well as dacarbazine and 5-fluorouracil (MPEP 804 "The specification can be used as a dictionary to learn the meaning of a term in the patent claims. *Toro Co. v. White Consul Indus. Inc.* 199 F.3d. 1295, 1299 (Fed. Cir. 1999)).

The interpretation of Stein, Blumenthal and Hansen and the motivation to combine the references is discussed supra.

At the time the invention was made, one skilled in the art would have been motivated and been assured of reasonable success in producing a composition comprising a humanized anti-CEA antibody such as the humanized MN-14 antibody and an apoptosis agent which synergize to produce a treatment effect in human thyroid cancer and human colon cancer. Griffiths claims the same composition (see Claims 1, 2 and 10 of Griffiths), Stein and Blumenthal disclose the specific cancers being effected by the MN-14 Mab and Stein discloses that the effect of MN-14 in combination with an apoptosis agent would synergize. Hansen specifically discloses and claims a humanized MN-14 antibody having the same binding properties as the murine Mab with reduced immunogenicity. One skilled in the art would have been assured of success in producing such compositions because both Griffiths and Hansen disclose compositions comprising naked humanized anti-CEA antibodies in combination with a therapeutic agent for treating cancer. Griffiths and Stein show that soluble or unconjugated apoptosis agents could be administered in combination with the antibody, and Stein teaches the synergy achieved with the antibody/ apoptosis combination. Additionally, one skilled in the art would have been motivated and been assured of success in producing the composition because the technology and reagents for producing the components were available at the time the invention was made, and were well known to one of ordinary skill in the art. Thus the claimed compositions were prima facie obvious at the time they were made over Claims 1, 2 and 10 of Griffiths and the disclosures of Stein, Blumenthal and Hansen.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER